REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments this application will contain claims 1-22 pending and under consideration. Claims 1, 16 and 22 have been amended for the purpose of expediting the prosecution of the application. The amendments to claims 1 and 16 are supported for example at page 7, lines 18-24 and Example 2. The amendment to claim 22 is supported for example at page 8, line 26 to page 9, line 16. No new matter is introduced by these amendments. It is believed that this Amendment and Reply addresses and overcomes all outstanding rejections. Accordingly, allowance of the application is solicited.

Claims 1-22 stand rejected under 35 USC § 103(a) as being unpatentable over Spanier et al. (US Patents 5011679 and 5114704) in view of Witt et al. (US Patent 6350438) and further in view of Perlberg et al. (US Patent 6223693). For the reasons detailed below, it is submitted that this rejection would be in error to the extent maintained against the amended claims.

Claims 1-15 and 22 of the application are directed to animal chew products, articles, or methods, that include or involve "an ingestible chew substrate" and "a cetyl pyridinium salt and sodium tripolyphosphate incorporated on or in said ingestible chew substrate", and further wherein "the animal chew product is effective to reduce the incidence of both gingivitis and dental calculus in an animal that chews the animal chew product." Claims 16-21 of the application are directed to methods for manufacturing animal chew products that

include “providing an ingestible chew substrate” and “incorporating sodium tripolyphosphate and a cetyl pyridinium salt on or in said substrate”, and further wherein “the animal chew product is effective to reduce the incidence of both gingivitis and dental calculus in an animal that chews the animal chew product.” In order for the current rejection of these claims to be proper, the cited prior art must, among other things, provide a reasonable expectation of success that a trial of the claimed combination would be successful. *In re Pantzer et al.*, 144 U.S.P.Q. 415 (CCPA 1965); *In re Longi et al.*, 225 U.S.P.Q. 645 (CAFC 1985). Further, the courts have long recognized that low levels of predictability exist in arts involving chemical reactions and physiological activity. *In re: Fisher*, 166 U.S.P.Q. 18 (CCPA 1970); *In re Hogan et al.*, 194 U.S.P.Q. 527 (CCPA 1977). Relatedly, obviousness determinations must be performed without “entry into the ‘tempting but forbidden zone of hindsight.’” *In re: Dembiczak*, 50 U.S.P.Q. 2d at 1616 (Fed. Cir. 1999). Taking these standards into account, the combination of references relied upon in the Office Action does not support a proper rejection under 35 USC § 103.

Example 2, beginning at page 12 of the application, describes a clinical study in which rawhide chew products incorporating the combination of sodium tripolyphosphate and cetyl pyridinium chloride were demonstrated to provide improved oral health including reductions in gingivitis and dental calculus (see Table 2, page 14, and comments thereon). The claims of the application have now all been amended to provide that the animal chew product incorporating the cetyl pyridinium salt and sodium tripolyphosphate “is effective to reduce the

incidence of both gingivitis and dental calculus in an animal that chews the animal chew product". Furthermore, the chew products incorporating the combination of sodium tripolyphosphate and cetyl pyridinium chloride provided reductions in dental plaque and mouth odor in the dogs, as also reported in Example 2. These efficacies could not have been reasonably expected by one of ordinary skill in the art prior to the Applicant's discovery.

In support, attached is the Declaration of Dr. George K. Stookey. Dr. Stookey has researched in dental health for over four decades, and has had a focus in researching systems for improving the dental health of companion animals, such as dogs and cats, for over two decades. He has authored or co-authored hundreds of papers appearing in scientific journals, as noted in his biographic information available at http://www.iusd.iupui.edu/depts/PCD/Faculty_Listing/Stookey.htm.

As averred by Dr. Stookey, at the filing date of this application, "...it would not have been possible to predict beforehand whether the incorporation of cetyl pyridinium chloride in the combination with STP in an animal chew product would provide a dental health benefit to animals." Dr. Stookey notes that none of the references cited in the current rejection describes any experiment in any animal. Dr. Stookey then goes on to cite examples from literature in which active agents (antimicrobial agents) that were known to be effective in other contexts were tried in animal chew products, but failed to demonstrate efficacy when tested on animals.

In particular, Dr. Stookey notes that hundreds of reports in the dental literature had documented the ability of topical rinses, solutions and gels containing chlorhexidine to reduce the formation of dental plaque, gingivitis and

periodontal disease as well as the development of dental caries in humans. Numerous reports in the dental literature also indicated that the application of these same products (particularly solutions and gels containing chlorhexidine) to experimental animals (typically rats and dogs) results in similar dental heath benefits. However, the incorporation of chlorhexidine into pet chew products did not help, as noted by Rawlings et al., J. Vet. Dent. 15:129-134 (1998). Dr. Stookey also notes a report by Brown et al., J Vet Dent 22(1); 16-19 (2005), in which the addition of a proprietary (unidentified) natural antibiotic to a pet chew product similarly did not help. Both of these literature references are attached to Dr. Stookey's Declaration and are also submitted in the attached Information Disclosure Statement.

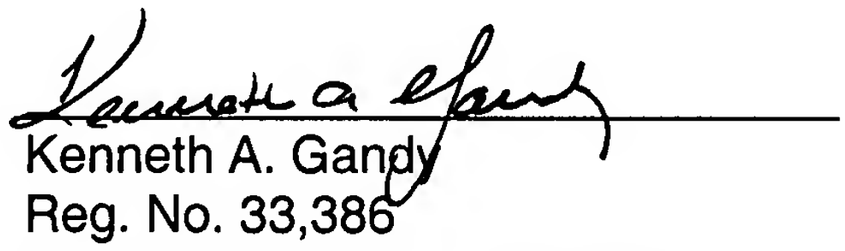
In summary, the invention claimed in the present case involves both chemical reactivity and physiologic response variables, recognized high contributors to unpredictability. Through actual testing and clinical trials the Applicant has discovered that the combination of sodium tripolyphosphate and cetyl pyridinium chloride is compatible and active (Example 1) and their incorporation and use in an animal chew product can lead to significant improvements in respect of both gingivitis and dental calculus, and also dental plaque and mouth malodor (Example 2). The prior art relied upon in the Office Action does not establish the necessary expectation of success for a rejection of the claimed invention for obviousness, as supported by the Declaration submitted herewith. Also, it is submitted that the references relied upon, and in particular the Witt et al. reference, lists a host of potential active agents, representing

thousands of potential combinations, and there is no particular guidance of the skilled artisan to select the combination of sodium tripoloyphosphate and cetyl pryidinium chloride, absent the use of hindsight.

For these reasons, it is submitted that the present claimed invention is not obvious when considered as a whole. Withdrawal of the rejection and allowance of this application containing claims 1-22 is therefore solicited.

The Applicant requests an opportunity for an interview of the Examiner if the Examiner believes that any objection or rejection could be maintained against the application as amended. The Examiner is requested to contact the undersigned attorney to arrange any such interview necessary.

Respectfully submitted,

By 

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